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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,953	12/30/2005	Stefan G. Pierzynowski	CU-4618 BWH	8692

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EXAMINER	
BLAKELY III, NELSON CLARENCE	
ART UNIT	PAPER NUMBER
1629	
MAIL DATE	DELIVERY MODE
03/30/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,953	PIERZYNOWSKI ET AL.	
	Examiner	Art Unit	
	NELSON BLAKELY III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-30 and 32-39* is/are pending in the application.

4a) Of the above claim(s) *7-28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 32-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

Claims 7-30 and 32-39 of the instant application are pending. Claims 7-28 and 30 are withdrawn pursuant to Applicant's Response, filed 02/16/2010. Accordingly, instant claims 29 and 32-39 are presented for examination on their merits.

Applicant's Arguments, filed 02/16/2010, have been fully considered. Rejections/objections not reiterated from previous Office Actions are hereby ***withdrawn***. The following rejections/objections are either reiterated or newly applied. They constitute the complete set of rejections/objections presently being applied to the instant application.

Election/Restrictions

It is noted wherein examination was drawn to Group II, a method of treatment for improving the absorption of amino acids in a vertebrate, comprising administering α-ketoglutarate. As per MPEP § 803.02, the Examiner will determine whether the entire scope of the claims is patentable. The elected subject matter is drawn to Group II, wherein the elected species, α-ketoglutarate (AKG), appears to be free of the art. The search has been expanded to include ornithine-AKG, arginine-AKG and glutamine-AKG, according to current Markush practice. Since the entire scope of the claims was not found to be allowable, claims to all other non-elected subject matter are held withdrawn from further consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 02/16/2010, has been entered.

Applicant's Amendment

Applicant's Amendment, filed 02/16/2010, wherein the specification and claims 29 and 38 are amended, claims 7-28 and 30 are withdrawn, and claims 1-6 and 31 are canceled, is acknowledged.

Claim Rejections - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plouvier *et al.* (US Patent Application Publication No. 2004/0127413A1; cited in a previous Office action), in view of Cynober *et al.* (J Trauma, Vol. 24, No. 7, Abstract; 1984).

With regard to instant claims 29 and 32-39, Plouvier *et al.* disclose in reference claims 1-3, 5-9, 33, 35, 41 and 42, pages 10 and 11, a method of treating a mammal in need of treatment, comprising administering a therapeutically effective amount of the enteric composition comprising at least one compound of the empirical formula (I) to the mammal, e.g., human being, suffering from digestive malabsorption and malnourishment, for example. In the instant excerpt, Plouvier *et al.* further disclose wherein the empirical formula (I), i.e., $(X)n_1Y(X)n_2$, comprises wherein X is ornithine, arginine, or glutamine, wherein n_1 is 1 and n_2 is 0, and wherein Y is alpha-ketoglutaric

acid (instant claim 29). In paragraphs **[0112]** and **[0116]**, page 5, Plouvier *et al.* disclose wherein the teachings relate to the use of a nutritional material for treating subjects in a malnourished condition, e.g., undernourished patients and anorexic subjects, and the use of enteric compositions for preparing a medicine intended to treat malnourished subjects, or animals. One of ordinary skill in the art, at the time of the invention, would have construed the term "animal" to include the subject matter of instant claims 32-36.

Plouvier *et al.* fail to disclose specifically wherein the amino acid is an essential amino acid, e.g., proline (instant claims 38 and 39). However, Cynober *et al.* disclose, in the abstract, a study to determine the effect of enterally administered ornithine-AKG on plasma and urinary amino acid levels after burn injury. In the instant excerpt, Cynober *et al.* disclose wherein plasma ornithine and proline increased until day 13 in the treated group, and wherein the results suggest that ornithine-AKG administration lowered protein catabolism after injury.

Therefore, a skilled artisan, at the time of the invention, would have envisaged the method of treatment for improving the absorption of amino acids, e.g., proline, in a vertebrate, comprising administering a composition comprising ornithine-AKG, for example, as disclosed by Plouvier *et al.*, in view of Cynober *et al.* One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a therapeutically effective medicament, with doses low enough to avoid unwanted side effects, in the treatment of a malnourished vertebrate. It

would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 29 and 32-39, is *prima facie* obvious over the combination of the aforementioned teachings.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to NELSON BLAKELY III whose telephone number is (571)270-3290. The Examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey S. Lundgren can be reached on (571) 272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614
March 27, 2011

/N. B. III/
Examiner, Art Unit 1614